

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today
(1) was not written for publication in a law journal and
(2) is not binding precedent of the Board.

Paper No. 33

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte IRVING BOIME

Appeal No. 95-2662¹
Application 07/771,262

HEARD: MAY 6, 1999

Before WILLIAM F. SMITH, ELLIS, and ROBINSON, **Administrative Patent Judges**.
ELLIS, **Administrative Patent Judge**.

DECISION ON APPEAL

This is an appeal under 35 USC § 134 from the final rejection of claims 1 and 12 through 15, all the claims pending in the application.

Claims 1 and 15 are illustrative of the subject matter on appeal and read as follows:

¹ Application for patent filed October 4, 1991.

1. A modified peptide or protein wherein said peptide or protein has biological activity, wherein said modification comprises an extension at the C- terminus consisting essentially of two or more tandem units wherein each unit independently consists of amino acid sequences found natively at positions 112-118 to position 145 of the beta subunit of human chorionic gonadotropin

15. The modified peptide or protein of claim 12 wherein said peptide or protein is luteinizing hormone (LH) or a follicle stimulating hormone (FSH).

The reference relied on by the examiner is:²

Boime et al. (Boime) WO 90/09800 (PCT) Feb. 21, 1989

The claims stand rejected as follows:³

- I. Claims 1 and 12 through 14 stand rejected under 35 USC § 112, first paragraph, as being non-enabled.
- II. Claims 1 and 12-15 stand rejected under 35 USC § 103 as being unpatentable over Boime.

We **reverse** both rejections.

² The examiner's Answer indicates that he additionally relies on Boime (Boime II), U.S. Patent 5,177,193 ('193), issued January 5, 1993 (filed June 1, 1990) and Shadle, U.S. Patent 4,847,325 ('325), issued July 11, 1989. However, the examiner has withdrawn the double patenting rejection of claim 1 over the '193 patent, see footnote 3, *infra*, and the claims which were rejected over the '325 patent; i.e, claims 9 and 10, have been canceled. Accordingly, we have considered the listing of these references to be an oversight on the part of the examiner.

³ The examiner has withdrawn the rejection of claim 1 under the judicially-created doctrine of obviousness-type double patenting over U.S. 5,177,193 which was present in the final office action (Paper No. 9). Answer, p. 2.

As set forth in the claims above, the present invention is directed to modified peptides or proteins which comprise a C-terminal extension of two or more tandem units of a carboxyl terminal peptide (CTP) derived from human chorionic gonadotropin (amino acid residues at positions 112-118 through 145 of the native beta subunit). In particular, the invention concerns the modification of pharmaceutical peptides. Specification, p. 1, para. 1. According to the specification, the addition of the CTP extension to a peptide results in an increase in its *in vivo* stability. Specification, p. 1, para. 1; p. 2, lines 11-29.

Enablement

The examiner argues that:

Enablement of the current specification as filed is not commensurate in scope with claims to modification of any peptide or protein other than FSH or LH. Applicants have demonstrated the attachment of the tandem CTP extension only to a single protein, FSH. ... there is no basis for the assumption that said extension would confer similar properties to other hormones, growth factors, cytokines, or other unrelated proteins. In the absence of **any** alternative embodiments, there is no basis to conclude that the innumerable claimed embodiments of the invention would function in an analogous manner to the single exemplified species [Answer, p. 5].

It is well established that the examiner may reject the claims as being based on a non-enabling disclosure when s/he has reason to conclude that one skilled in the art would be unable to carry out the claimed invention without undue experimentation.

In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991);

In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) (“a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the

subject matter sought to be patented **must** be taken as in compliance with the enabling requirement of the first paragraph of § 112 **unless** there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support”).

Here, we do not find that the examiner has applied the appropriate legal standard for determining whether a specification provides an enabling disclosure. We caution the examiner that the initial burden lies with her **to provide reasons**, preferably supported with factual evidence, as to why it would require undue experimentation for one skilled in the art to make and use the invention as claimed. The factors to be considered in determining whether a disclosure would require undue experimentation have been set forth by the court in ***In re Wands***, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The examiner has not provided any reasons as to why one skilled in the art would (i) have “no basis to conclude” that the addition of the claimed C-terminal extension would confer similar properties to other unrelated proteins, and (ii) not have been able to make and use the claimed invention throughout its scope, absent undue experimentation. Accordingly, we must reverse this rejection.

Obviousness

The examiner has predicated her conclusion of obviousness on the teachings of

Boime, a reference which discloses, *inter alia*, the addition of a C-terminal extension comprising from about amino acid residues 112-118 through 145 of human chorionic gonadotropin to follicle-stimulating hormone (FSH) and to luteinizing hormone (LH).

The examiner acknowledges that the Boime reference differs from the claimed invention in that only a single CTP extension is used rather than two or more tandem CTP extensions. Answer, p. 4, first complete para. The examiner argues, however, that :

The '800 [Boime] publication discloses the extensive O-linked glycosylation as being responsible for the increased half-life of the protein. Given this, it would have been obvious to one of ordinary skill in the art that further increasing the level of glycosylation would be reasonably expected to further decrease plasma clearance, and that a reasonable way to achieve this would [be] by reiteration of the CTP peptide bearing glycosylation sites. [Answer, p. 4, para. 2].

We find the examiner's position untenable.

It cannot be gainsaid that the examiner has the initial burden under 35 USC § 103 of presenting a *prima facie* case of obviousness. *In re Piasecki*, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-88 (Fed. Cir. 1984). Before a conclusion of obviousness can be made based on a single reference, or a combination of references, there must have been a reason, motivation or suggestion in said reference(s) to make the claimed invention.

Pro-Mold & Tool Co. V. Great Lakes Plastics, inc., 75 F3.d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996); *In re Ochiai*, 71 F3.d 1565, 1570, 37 USPQ2d 1127, 1131 (Fed. Cir. 1995) ("The mere chemical possibility that one of those prior art acids could be modified such that its use would lead to the particular cephem recited in claim 6 does not make the process recited in claim 6 obvious 'unless the prior

art suggested the desirability of [such a] modification”). Here, the examiner has not provided any factual evidence, or sound scientific reasoning, as to why “the ordinary artisan would have recognized that ‘if some is good, more is better.’” Answer, p. 6. As pointed out by the appellant, this is not a generically true proposition. Reply Brief, p. 2. For example, in the medical arts, “more” may be lethal; e.g., “more” of a drug can result in an overdose. **Id.** As to the examiner’s statement that he “feels that the invention [sic, would have been] immediately obvious to the ordinary artisan upon reading the ‘800 [Boime] disclosure, and asserts that the ordinary artisan would immediately envision how to carryout such a modification,”⁴ we remind him that a conclusion of obviousness must be based on fact, not unsupported assertions and generalities. **In re Freed**, 425 F.2d 785, 787, 165 USPQ 570, 571 (CCPA 1970); **In re Warner** 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), **cert. denied**, 389 U.S. 1057 (1968). Accordingly, we reverse the rejection.

The decision of the examiner is reversed.

⁴ Answer, p. 7.

Appeal No. 95-2662
Application 07/771,262

REVERSED

William F. Smith
Administrative Patent Judge

Joan Ellis
Administrative Patent Judge

Douglas W. Robinson
Administrative Patent Judge

)
)
)
)
)
) BOARD OF PATENT
)
) APPEALS AND
)
) INTERFERENCES
)
)
)

dm

Morrison & Foerster
2000 Pennsylvania Avenue, N.W.
Suite 5500
Washington, D.C. 20006-1812

Appeal No. 95-2662
Application 07/771,262